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Original Research Article

Impact of family DOTS on tuberculosis treatment outcomes and associated factors in tribal and hard to reach areas in the state of Chhattisgarh: an implementation research

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ABSTRACT

Background: Tuberculosis (TB) remains a worldwide healthcare problem and it is one of the major public health concerns in India including Chhattisgarh state. National tuberculosis elimination program (NTEP) has adopted direct observed treatment (DOTS) strategy for elimination of TB. Due to inaccessibility and difficult to reach areas in the tribal areas, monitoring of treatment adherence and treatment completion remains a challenge leading to poor treatment outcomes among TB cases. This implementation research was aimed to assess the impact of family DOTS on the TB treatment outcomes in a tribal district of Chhattisgarh.
Methods: A prospective cohort study of all new smear positive sputum, new smear negative sputum and extra-pulmonary TB patients who were newly diagnosed and registered for treatment under the revised national tuberculosis control programme (RNTCP) in hard to reach district was implemented between November 2016 to January 2018. They were followed till the completion of the treatment.
Results: Total 305 tuberculosis new patients (218 intervention and 87 in comparison blocks) were registered for treatment at health facilities in study area. The treatment success rate in the comparison group was better (72.41%) compared to the intervention group (68.35%). Similar results have been observed in terms of non-adherence to treatment and death rate. Sputum conversion rate was observed to have 94% in intervention group in comparison to 95% comparison group.
Conclusions: Family DOTS may not be effective unless there is involvement from the RNTCP by regular monitoring and follow up.

Keywords: Family DOTS, Hard to reach area, Implementation research, NTEP, TB

INTRODUCTION

TB still remains a worldwide healthcare problem. Globally, the burden of TB is estimated to be highest in Asian countries.[1] It is still one of the leading killer diseases although there is a medicine for complete cure which was available since 1943. This indicates that medicine alone cannot eliminate the disease. Solution for the problem has to be looked beyond drug. As per the RNTCP guideline in India currently known as NTEP, DOTS is the key strategy for the control and treatment of the TB patients.[2] It is aimed to improve patient adherence to treatment and completion through the appointment of treatment supervisors. A DOTS provider can be any person who is acceptable and accessible to the patient and accountable to the health system, except a family

member.[3] But this has been a challenge to implement in the state. It is more challenging especially in the hard to reach and conflict areas. Alternative thought suggests that family member can be a better DOTS provider. A classic study from Chennai, India showed that supervised domiciliary care was as effective as hospital-based care in achieving treatment success.[4] There are other studies which support the concept of family DOTS which were implemented in Gujarat, India, Nepal, Pakistan, Sri Lanka, Thailand, east Azerbaijan province located in north west of Iran.[8-14] This implementation research was aimed to examine the effect of family DOTS on treatment outcome of among new TB patients (pulmonary and extra pulmonary) in hard to reach area in one of the tribal district of Chhattisgarh, India.

METHODS

Study design

The study design was a prospective cohort of all new smear positive sputum, new smear negative sputum and extra-pulmonary TB patients who were newly diagnosed and registered for treatment under the RNTCP in 3 blocks of Kondagaon district. They were followed till the completion of the treatment from 1 January 2017 to 31 January 2018. All blocks of the district were divided into two groups that is, intervention group (3 blocks Kondagaon, Makdi, Pharsgaon) and comparison group (2 blocks Keshkal and Vishrampuri). Both groups had been selected randomly. The names of all blocks were written in different piece of papers and 3 blocks were randomly picked up to select intervention group. In the intervention group DOTS providers were family members. The comparison group had standard DOTS providers. The study was implemented in the existing programme setting as implemented in the district. Ethics approval was obtained from institutional ethics committee. The analysis for treatment outcome was performed using epi-info version 7.2. Odds ratios (OR) and 95% confidence intervals (CI) were used for the interpretation of analysis.

Sample size

The sample size was estimated based on the TB India annual report 2014 of Chhattisgarh which showed 80% cure rate among new smear positive patients. Since the report did not contain the district details about the performance on the treatment success cumulative state figour was considered as base to calculate the sample size for the study. Assuming that the treatment success rate in Chhattisgarh was 80%, the sample size estimated to be 275 new TB cases in each group in order to have a 50% increase in treatment success with a power of 90% at 5% significant level. The study assumes 5% attrition rate.

Inclusion criteria

All newly diagnosed sputum smear positive, sputum negative and extra-pulmonary TB patients who were registered for treatment in public health facilities residing in Kondagaon district were included in the study.

Exclusion criteria

Multidrug-resistant TB cases and previously treated cases that is, relapse, treatment after default and failure cases, patients with HIV co-infection or non-tuberculosis mycobacterium (NTM) infections, TB patients getting treatment from private physicians and patients residing outside the intervention blocks in the district were excluded in the study.

RESULTS

Total 305 tuberculosis new patients (218 intervention and 87 in comparison blocks) were registered for treatment at health facilities in study area. 50% (n=218) of the cohort were sputum smear-positive, 40% were sputum smear-negative and 10% were extra pulmonary TB patients. The median age of the subject was 35 years (range 5-80 years) and 71% were males in the intervention blocks. The characteristics of family DOTS providers indicate that 23% of them were sons followed by wife 17%, brother 13% and husband 12%.

The median age of the family DOTS providers was 28 years (range 12-65 years) and 58.55% were males. 27.78% of the family DOTS providers were illiterate and 38% of them had either studied up to high school or intermediate. 24% of study subjects of intervention block used alcohol and tobacco products simultaneously. The sputum conversion rate among those who tested sputum after intensive phase was 94% in the intervention group and 95% in the control group this rate was higher among control group was statistically not significant (OR=0.772; 95% CI=0.133-4.9434; p=0.77) and the treatment success rate in the intervention was 68.35% (149/218) as compared to 72.41% (63/87) in the control group. It was observed that such rate was 4% higher among control groups. But the difference was statistically not significant (OR=0.82; 95% CI=0.474-1.428; p=0.486).

Death rate in the intervention group was 11% (24/218) of the total case registered compared to 9% (8/87) in the control group. Hence death rate was 1% higher in the intervention. However this association is statistically not significant (OR=1.22; 95% CI=0.526-2.839; p=0.641). Non-adherence to treatment indicate that 24% (8/35) went to local healers for the treatment; 18% (6/35) were alcohol users who stopped medicine, 9% (3/35) had stopped medicine because they were vomiting after taking medicines and 6% (2/35) changed the treatment course from allopathic treatment to Ayurveda system of medicine. Remaining 11% (4/35) of them left medicine because they felt better after taking treatment for some time and 32% (11/35) of them left medicine for unknown reasons.

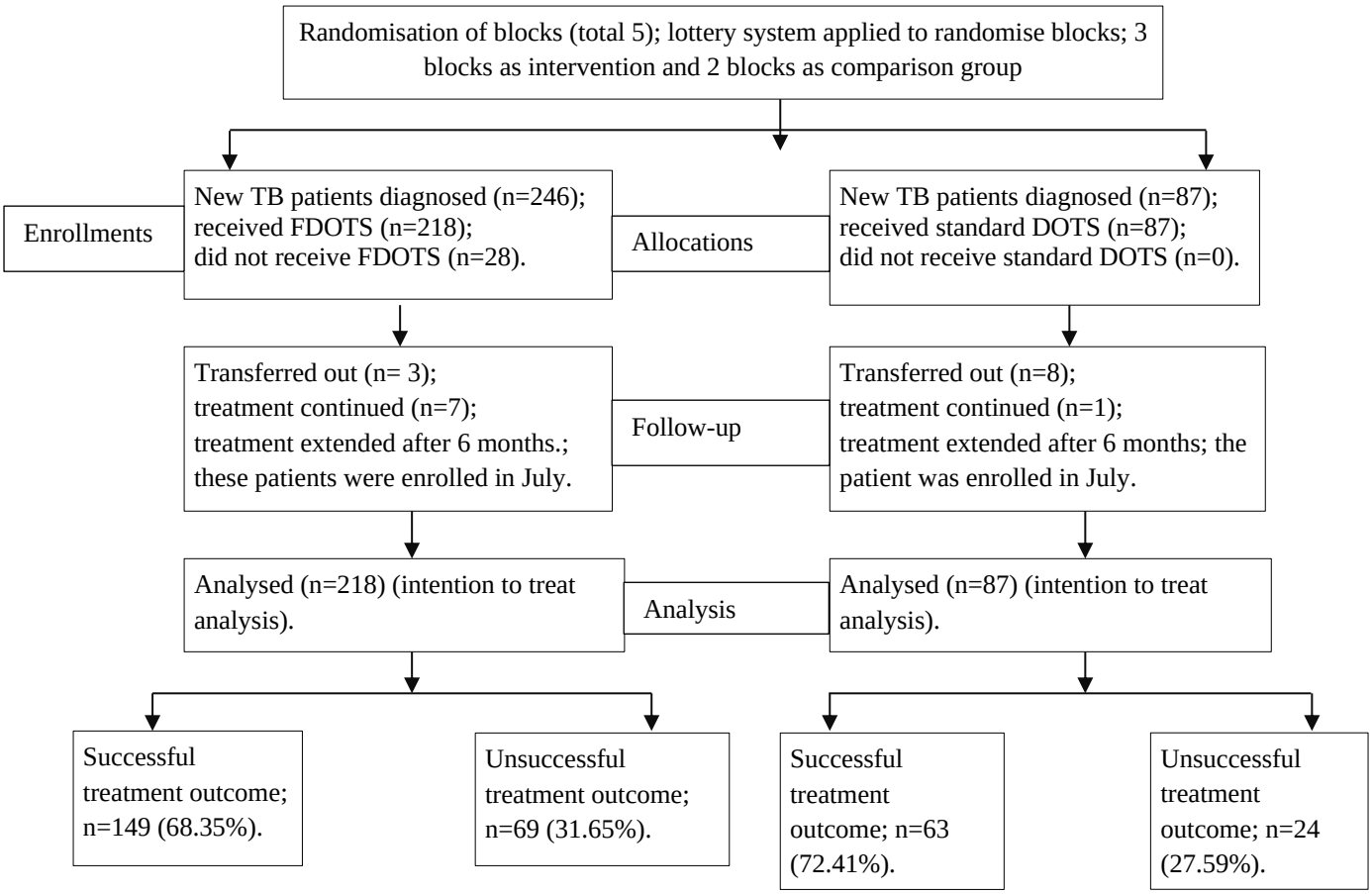

Figure 1: Intention to treat analysis.

Table 1: General characteristics of TB patients.

Variables	Intervention blocks		Comparison blocks	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Age (in years)				
<10	7	3.21	1	1.15
11 to 20	22	10.09	10	11.49
21 to 30	62	28.44	19	21.84
31 to 41	44	20.18	16	18.39
41 to 50	42	19.27	26	29.89
>50	41	18.81	15	17.24
Total	218	100	87	100
Gender				
Male	155	71.10	64	73.56
Female	63	28.90	23	26.44
Total	218	100	87	100
Education				
Illiterate	109	50	31	35.63
Primary	44	20.18	20	22.99
Middle	31	14.22	14	16.09
High school	11	5.05	6	6.90
Inter	20	9.17	9	10.34
College	3	1.38	7	8.05
Postgraduate	0	0.00	0	0.00
Total	218	100	87	100

Continued.

Variables	Intervention blocks		Comparison blocks	
Use liquor, tobacco, smoking, gutka				
Only liquor	27	12.39	6	6.90
Liquor and any one other	40	18.35	13	14.94
Liquor and more than one other	13	5.96	3	3.45
No liquor	121	55.50	39	44.83
Status unknown	14	6.42	10	11.49
No liquor but other substance	3	1.38	16	18.39
Total	218	100	87	100
Disease classification				
Smear positive	108	49.54	53	60.92
Smear negativw	88	40.37	27	31.03
Extra pulmonary	22	10.09	7	8.05
Total	218	100	87	100

Table 2: General characteristics of family DOTS providers.

Variables	Frequency	Percentage (%)
Son	54	23.08
Daughter	13	5.56
Husband	27	11.64
Wife	40	17.00
Brother	30	12.82
Sister	20	8.55
Father	15	6.41
Mother	13	3.42
In laws	8	5.56
Grandson	5	2.14
Others	9	3.85
Total	234	100
Age (in years)		
11 to 20	52	22.22
21 to 30	91	38.89
31 to 40	59	25.21
41 to 50	31	13.25
>50	1	0.43
Total	234	100.00
Gender		
Male	137	58.55
Female	97	41.45
Total	234	100
Education		
Illiterate	65	27.78
Primary	38	16.24
Middle school	30	12.82
High school	45	19.23
Intermediate	45	19.23
College	9	3.85
Postgraduate	2	0.85
Total	234	100.00

Table 3: Success at the end of treatment (n=305).

Outcomes	Family member DOTS		Standard DOTS		Odds ratio	95% CI
	Frequency	%	Frequency	%		
Total	n=218		n=87			
Conversion rate (after IP)	125	94	59	95	0.629	0.136-2.902
Treatment success	149	68.35	63	72.41	0.822*	0.475-1.425
Non-adherence	35	19.00	07	10.00	2.185*	0.931-5.129
Death	24	11.00	08	9.20	1.221*	0.526-2.825
Transferred out	03	1.38	08	9.20	0.137*	0.035-0.532
Treatment continued	07	3.21	01	1.15	2.853*	0.345-23.539

*Conversion rate includes sputum smear positive pulmonary TB only; *treatment success includes cure and treatment completed together.

DISCUSSION

As per RNTCP guideline a DOTS provider can be any person who is acceptable and accessible to the patient and accountable to the health system, except a family member.[3] Ongoing health education and counselling is needed to both family members and patients. In current study treatment success rate in study group was in the range of 68-72% which was higher than study done by Minaleshewa Biruk et al and Pamela Weiss et al was in the range of 60-65% but lower than 92.5% observed by Assefa Tola et al in a similar kind of cohort study.[4-6] Current study reveals 94% sputum conversion rate among new smear positive cases among study group was much higher than the study done by S Bawri et al was 84% at the end of intensive phase.[7] The findings of this study showed that family DOTS and standard DOTS strategies had similar treatment outcome while in a similar study done by Yekrang Sis H et al revealed that the advantages of standard-DOTS strategy over family-DOTS in terms of treatment outcome.[10] Our study depicted 68-72% clinical result and in a similar study it was 80% done by Yekrang Sis H et al at lung diseases research centre of Tabriz.[10] However the practice of family-member as DOTS providers was very common in the control group as 54% had family members as DOTs provider in the control group too. The study showed that about such practice may be an obstruction to the set a target for complete elimination of TB by 2025, five years ahead of the global target of 2030. WHO has recommended that TB should be treated in the living place of the patients under the supervision of health care providers.[15] Our study supports this strategy with deferent profile of DOTS in both study group had similar treatment outcome. The study showed that the use of alcohol and tobacco products were very common among the patients. About 39% of the patients in the intervention blocks and about 36% patients in the control blocks were found to be using alcohol and tobacco. Different studies suggest that alcohol consumption has adverse impact on the TB treatment outcome.[16-19] Health education and counselling is a must for such patients to improve TB treatment outcome. The counselling by family members may not be an effective strategy to deal such patients. Family DOTS could be the effective strategy for frontline care providers, improve quality of life in both patients and their families.

Limitations

First, the study was performed in a programmatic setting and used programmatic definitions for treatment outcomes. Some of those patients who were not improving were sent for further checkups to tertiary hospitals. One young tribal boy who had undergone TB treatment for extra pulmonary TB was diagnosed with a low malignancy tumour at AIIMS Raipur. There was a short supply of ATT drugs to TB patients for about three months between August to November 2017. Patient residing near to PHCs were supplied medicine on weekly basis and patients residing far were supplied on monthly basis. Sometimes patients had to skip medicine due to non-availability of drugs. Initially the intervention relied on the existing RNTCP staff for the allocation of family DOTS, training to patient and family members. But the follow up of study subjects was limited due to various reasons. Geographical barriers and conflict situation acted as barriers to the programme implementation for patient follow up. A block with a high number of TB patients but only one senior treatment supervisor was badly affected.

CONCLUSION

Family DOTS may not be effective unless there is involvement from the RNTCP by regular monitoring and follow up.

Recommendations

No significant differences being found between family DOTS and standard DOTS. It is, therefore, the family DOTS may not be an effective strategy to monitor treatment outcome of TB patients in comparison to standard DOTS. However exploratory study could be done in deferent study settings seeking any advantage of family DOTS. Although family DOTS have less or equal impact on treatment outcome yet the standard DOTS can be used wherever the community DOTS providers are not effective enough or patients reside in a hard to reach areas.

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